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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,957	03/07/2002	Kenneth M. Yates	CARR-0083 (103216.00251)	7354
25555	7590	11/05/2003	EXAMINER	
JACKSON WALKER LLP 2435 NORTH CENTRAL EXPRESSWAY SUITE 600 RICHARDSON, TX 75080			PRATS, FRANCISCO CHANDLER	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/092,957	YATES ET AL.	
	Examiner	Art Unit	
	Francisco C Prats	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-63 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-63 are presented for examination.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-5, 11 and 12, drawn to a substantially dry mixture comprising a plant solid, which may be Aloe vera solid comprising more or less than 50% water soluble complex carbohydrate, and a water-soluble pharmaceutical auxiliary, wherein said mixture may be in powder drink mix form, tablet or capsule form, classified at least in class 514, subclass 772.3, and class 424, subclasses 489 and 451.
- II. Claims 1 and 6, drawn to a dry mixture comprising a plant solid and polyvinylpyrrolidone, classified in class 514, subclass 772.3.
- III. Claims 1 and 7, drawn to a dry mixture comprising a plant solid and carboxymethyl cellulose, and/or microcrystalline cellulose, and/or ammonium lauryl sulfate, and/or magnesium stearate, classified in class 514, subclass 781.

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IV. Claims 1, and 8-10, drawn to a substantially dry mixture comprising a plant solid, a water-soluble pharmaceutical auxiliary, and a simple sugar and/or starch, classified in class 514, subclass 777.

As an aside note that the term "maltodextran" is a misspelling of the term -- maltodextrin --.

V. Claims 13-15, 20, 21, 30-33, 37, 38 drawn to a substantially dry mixture comprising Aloe vera solid and polyvinylpyrrolidone, wherein said mixture may be in powder drink mix form, tablet or capsule form, classified at least in class 424, subclasses 744, 489 and 451.

VI. Claims 13 and 16, drawn to a substantially dry mixture comprising Aloe vera solid and carboxymethyl cellulose, and/or microcrystalline cellulose, and/or ammonium lauryl sulfate, and/or magnesium stearate, classified in class 424, subclass 744.

VII. Claims 13 and 17-19, drawn to a substantially dry mixture comprising Aloe vera solid and a simple sugar and/or starch, classified in class 424, subclass 744..
Note again that the term "maltodextran" is a misspelling of the term -- maltodextrin --.

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VIII. Claims 22-25, drawn to a substantially dry mixture comprising Aloe vera solid, a water-soluble pharmaceutical auxiliary, and a starch, classified in class 424, subclass 744.

IX. Claims 26-29, drawn to a substantially dry mixture comprising Aloe vera solid, a water-soluble pharmaceutical auxiliary, and a simple sugar, classified in class 424, subclass 744.

X. Claims 30 and 34-36, drawn to a substantially dry mixture comprising Aloe vera solid, polyvinylpyrrolidone, and a simple sugar and/or starch, classified in class 424, subclass 744.

XI. Claims 39-41, 45 and 46, drawn to a substantially dry mixture comprising Aloe vera solid, polyvinylpyrrolidone and maltodextrin, wherein said mixture may be in powder drink mix form, tablet or capsule form, classified at least in class 424, subclasses 744, 489 and 451.

Note yet again the misspelling of the term -- maltodextrin -- as "maltodextran."

XII. Claims 39 and 42-44, drawn to a substantially dry mixture comprising Aloe vera solid,

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polyvinylpyrrolidone and maltodextrin, classified in class 424, subclass 744.

XIII. Claims 47-52 drawn to a substantially dry mixture comprising Aloe vera solid, polyvinylpyrrolidone, maltodextrin, and fructose, classified in class 424, subclass 744.

As an aside, note that claim 50 recites a composition comprising less than 50% water soluble Aloe carbohydrate, yet depends from claim 49, which recites a composition comprising more than 50% water soluble Aloe carbohydrate. Thus, claims 49 and 50 are mutually exclusive.

XIV. Claims 53-55, drawn to a method for dispersing in water a complex carbohydrate from a processed plant by mixing the carbohydrate with a pharmaceutical auxiliary which may be polyvinylpyrrolidone, classified in class 514, subclass 772.3.

XV. Claims 53 and 56, drawn to a method for dispersing in water a complex carbohydrate from a processed plant by mixing the carbohydrate with a pharmaceutical auxiliary which may be carboxymethyl cellulose, and/or microcrystalline cellulose, and/or ammonium lauryl

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sulfate, and/or magnesium stearate, classified in class 514, subclass 781.

XVI. Claims 60-63, drawn to a method for dispersing in water a processed Aloe vera solid by mixing the carbohydrate with a starch, classified in class 514, subclass 777.

Product inventions I through XIII include inventions which are subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, the inventions claimed generically as dry compositions comprising Aloe or plant solid have separate utility such as uses in non-aqueous, i.e., "substantially dry," skin lotions. See MPEP § 806.05(d). Moreover, each of groups I through XIII recites a different product having different ingredients and/or combinations of ingredients and/or different physical forms. Thus, because of the multitude of different embodiments recited in the claims, ranging from the generic use of any pharmaceutical auxiliary with any substance obtained from a plant, to specific combinations of ingredients, it is clear that the search for each any one group would not be the same for any other group. Moreover, a reference which would anticipate any one group would not anticipate or necessarily render obvious

another group. Because, on the current record, each of the numerous claimed product embodiments would appear to be capable of supporting a separate patent, restriction is clearly proper.

Also, several of the various claimed product inventions have combination/subcombination relationships. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). The combinations do not require the particulars of the subcombination as claimed for patentability because the combinations, due to the presence of additional ingredients, would be patentable even if the subcombinations were known and obvious, assuming that the prior art did not teach or suggest the presence of the additional ingredients recited in the combination claims. Moreover, the subcombinations have separate utility, as discussed above, such as ingredients in non-aqueous, i.e., "substantially dry," skin lotions.

Inventions I-XIII are related to inventions XIV-XVI as products and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced

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with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the products clearly can be used in materially different processes, such as the treatment of disorders known to be treatable using Aloe products, without the pre-dispersion in water recited in the process claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classifications and recognized divergent subject matter, restriction for examination purposes as indicated is proper. Moreover, because these inventions are distinct for the reasons given above and the search required for any one group is not required for another group, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection

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are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Francisco C Prats', is positioned above the printed name and title.

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP